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25

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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/814,025	14,025 03/31/2004		James Rasmussen	GC22.4-CON2	4968
24536	7590	03/18/2005		EXAMINER	
GENZYME			SULLIVAN, DANIEL M		
LEGAL DEF		NT DNNECTOR		ART UNIT	PAPER NUMBER
		01701-9322	1636		

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

1			
	Application No.	Applicant(s)	
Office Action Comments	10/814,025	RASMUSSEN ET AL.	
Office Action Summary	Examiner	Art Unit	
The MAILING DATE of this communication and	Daniel M. Sullivan	1636	
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address	
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	6(a). In no event, however, may a reply be tim within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONED	ely filed swill be considered timely. the mailing date of this communication. O (35 U.S.C. § 133).	
Status			
1) Responsive to communication(s) filed on 2a) This action is FINAL . 2b) This 3) Since this application is in condition for allowan closed in accordance with the practice under <i>E</i> .	action is non-final. ce except for formal matters, pro		
Disposition of Claims			
4) Claim(s) <u>48-72</u> is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) <u>48-72</u> are subject to restriction and/or	n from consideration.		
Application Papers			
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the consequence of the conseque	epted or b) objected to by the E Irawing(s) be held in abeyance. See on is required if the drawing(s) is obj	37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priori application from the International Bureau * See the attached detailed Office action for a list of	have been received. have been received in Application ty documents have been receive (PCT Rule 17.2(a)).	on No d in this National Stage	
Attachment(s)			
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary (Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:		

DETAILED ACTION

The Preliminary Amendments filed 31 March 2004 and 3 June 2004 have been entered. Claims 48-72 are presently pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 48-59, drawn to a method for producing a glucocerebrosidase from a culture of mammalian cells, classified in class 435, subclass 70.1.
- II. Claims 60-66, drawn to a composition comprising a glucocerebrosidase containing a higher number of exposed mannose residues than human placental glucocerebrosidase, classified in class 435, subclass 200.
- III. Claims 67-72, drawn to a method of treating a human patient having Gaucher's disease comprising administering a composition comprising a glucocerebrosidase containing a higher number of exposed mannose residues than human placental glucocerebrosidase, classified in class 424, subclass 94.61.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product made can be made by any method of protein synthesis, such as chemical synthesis or expression in non-mammalian cells, with the exposed mannose residues added *in vitro*.

Application/Control Number: 10/814,025

Art Unit: 1636

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the glucocerebrosidase can be used in processes other than a method of treatment. For example, the polypeptide can be used as a standard in an assay to detect the presence of a glucocerebrosidase in a sample or as a standard in an assay do determine glucocerebrosidase enzyme activity in a sample.

Although the Office acknowledges that in the event a product claim is deemed allowable, determining patentability of process claims that depend from or otherwise include all the limitations of the allowable product claim does not impose an undue burden (see below), no such determination of patentability has been made in the instant case. In the event that the product is not patentable, a determination of whether each method of making and using the product is patentable over the art is based upon the particulars of the method and not on the product made by or used in the method. Therefore, until the product is deemed allowable, search and examination of the process claims with the product imposes an undue burden on the Office. As discussed in detail below, if a product claim is found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Groups I and III are directed to distinct methods. Group I is directed to a method of producing a protein and comprises process steps that lead to production of a glucocerebrosidase containing a higher number of exposed mannose residues than human placental

glucocerebrosidase. The method of Group III is not limited to comprising steps that lead to production of a glucocerebrosidase and comprises steps, such as administering a composition comprising a glucocerebrosidase to a patient having Gaucher's disease, that are not comprised in the method of Group I.

In the absence of an allowable product which the process claims are limited to making or using, examining the methods of Groups I and III together in a single application would impose a serious burden on the Office. *Prima facie* evidence for the additional burden imposed by examining each additional method is evidenced by the separate classification of the methods. Furthermore, as each method is limited to comprising elements to which the other method is not limited, examination of each method requires a separate search for those elements that distinguish the respective methods. In addition, because each method encompasses subject matter not encompassed by the other method, a determination that any one method is patentable over the art does not adequately support patentability of any of the other methods. Therefore, patentability of each method must be determined separately.

Rejoinder in view of In re Ochiai, In re Brouwer

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Application/Control Number: 10/814,025 Page 5

Art Unit: 1636

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Art Unit: 1636

Species election

This application contains claims directed to the following patentably distinct species of the claimed invention: The product of Group II and the methods of Groups I and III, wherein the inhibitor of carbohydrate processing is selected from the group consisting of deoxymannojirimycin, swainsonine, castanospermine, deoxy-nojirimycin and N-methyldeoxynojirimycin. Absent evidence to the contrary, each of the distinct inhibitors of carbohydrate processing would produce a glucocerebrosidase comprising a different pattern of glycosylation and, therefore, having distinct structural and functional properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 48 is generic to the species set forth in claims 49-53, claim 54 is generic to the species set forth in claims 55-59 and claim 67 is generic to the species set forth in claims 68-72.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/814,025 Page 8

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.

Examiner

Art Unit 1636